

# **EXHIBIT A**



Atty Dkt. No. PP01631.002

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

BARNETT et al.

Serial No.: 09/475,704

Art Unit: 1635

Filing Date: December 30, 1999

Examiner: B. Whiteman

Title: POLYNUCLEOTIDES ENCODING ANTIGENIC HIV TYPE C  
POLYPEPTIDE, POLYPEPTIDES AND USES THEREOF

DECLARATION PURSUANT TO 37 C.F.R. § 1.132 OF JOHN J. DONNELLY, Ph.D.

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

I, John J. Donnelly, hereby declare as follows:

1. I received my Bachelors of Science Degree in Biology from the University of Pennsylvania in 1975 and a Doctorate of Philosophy Degree in Immunology in 1979 from the University of Pennsylvania. I also have a Masters of Sciences Degree in Strategic Studies from the U.S. Army War College.
2. I am currently Senior Director, Vaccine Research and Development in the Department of immunology & Infectious Diseases at Chiron Corporation and have been at Chiron since 1998. Before joining Chiron, I was Associate Director, Immunology Dept. of Virus & Cell Biology at Merck. Additional details regarding my background and qualifications can be found in the accompanying copy of my *Curriculum Vitae* (Exhibit A).

3. I have reviewed pending Patent Application Serial No. 09/475,704 for "POLYNUCLEOTIDES ENCODING ANTIGENIC HIV TYPE C POLYPEPTIDE, POLYPEPTIDES AND USES THEREOF" by Barnett, et al., (hereinafter "the specification") and the currently pending claims. I have also reviewed the Office Action dated July 18, 2002. Therefore, I am familiar with the issues raised by the Examiner in the Office Action.

4. I understand that the pending claims are directed to expression cassettes comprising nucleotide sequences that encode immunogenic HIV Gag polypeptides. Further, the Gag-encoding nucleotide sequence must exhibit at least 90% identity to the sequences of SEQ ID NOs:1-4. It is further my understanding that the claims are also directed to cells comprising these polynucleotides and to methods of generating an immune response in a subject using the claimed polynucleotide sequences.

5. It is my opinion that, as a technical matter, a skilled worker could have readily made and used the compositions and methods of the pending claims in light of the specification, together with the common general knowledge, tools and methods available in December 1999. I base this opinion on the facts set forth below; however, I call attention to the fact that it was considered routine experimentation at the time of filing to determine a sequence having (i) at least 90% sequence identity to SEQ ID NO:1-4 and (ii) encoding an immunogenic Gag polypeptide; to express such polynucleotides in stem cells or their progenitors; to deliver in a variety of ways such polynucleotides to generate an immune response in a subject. In addition, in drawing my conclusions, I have considered the nature of the claims, the quantity of experimentation required to practice the subject matter of the claims, the existence of working examples, the direction present in the specification, the state of the field at the time the application was filed and the level of skill in the art.

6. At the outset, I note that the term "skilled worker" with a routine level of skill in the field of molecular biology, immunology and nucleic acid delivery in

December 1999 had a Ph.D. degree and two or more years of post-doctoral training. In view of my training and experience, I am currently, and was in December of 1999, such a skilled worker.

7. In December 1999, the quantity of experimentation required to identify sequences exhibiting 90% identity to SEQ ID NOs:1-4 was quite low. For example, BLAST software programs were commonly known and readily available on the Internet at this time. This set of programs allows for an easy alignment and determination of percent identity as between any sequences. The skilled worker could have easily used the BLAST or any number of other similar programs to determine the percent identity between sequences (in this case between any given sequence and those presented SEQ ID NOs:1-4). The specification also provides extensive guidance in this regard, for example, on page 17, line 3 through page 19. Working examples are also provided, for example comparisons of the claimed sequences to wild-type HIV sequences. (See, Figure 5). Furthermore, the skilled worker could have readily generated any sequence falling within the scope of the claims using routine methods, for example by utilizing PCR to generate sequences, by introducing point mutations and the like. Thus, it is my opinion that it would have required only routine experimentation to determine sequences falling within the 90% identity, as claimed.

8. In addition, the specification provides significant direction for evaluating whether sequences having 90% identity to SEQ ID NO:1-4 encode an immunogenic Gag polypeptide. Those of us working in the field of gene delivery and immunology are well versed in the various tests for determining immunogenicity, which include computer analysis of sequences, comparison to known immunogenic sequences as well as functional tests (e.g., ELISAs, CTL assays and others described in the Examples of the specification). Examples present in the specification demonstrate the generation of sequences and immunogenicity testing of these sequences. (See, Examples 1 and 4).

9. Furthermore, the state of the art in December 1999 was quite sophisticated with regard to determining both sequence identity and evaluating immunogenicity. I have described above some of the tools, programs and methods available in the field of recombinant nucleic acid technology in December 1999 and many other examples of homologous nucleic acid molecules that encode immunogenic proteins were also available. Therefore, it is my opinion that, following the guidance of the specification, a scientist could have readily made and used polynucleotide sequences that exhibit at least 90% sequence identity to SEQ ID NO:1-4 and which encode an immunogenic HIV Gag polypeptide.

10. Preparing polynucleotides encoding immunogenic Gag polypeptides in December 1999 was a predictable art. There is no doubt that a skilled worker would have been able to make and use sequences exhibiting 90% identity to SEQ ID NO:1-4 and encoding an immunogenic polypeptide. Even if a rare construct were inoperable for some reason (*e.g.*, it wasn't immunogenic), the skilled worker would have readily modified the construct according to the alternatives available at the time and described in the specification. In other words, to the skilled worker, an inoperable construct would itself be a useful starting material for other operable constructs. Essentially all molecules that fall within the claims would be useful for making or using defining technical features of the claims, *i.e.*, nucleotide sequences having 90% sequence identity to SEQ ID NO:1-4 and which encoded an immunogenic HIV Gag polypeptide.

11. Similarly, the specification as filed clearly provides ample guidance on how to generate an immune response (humoral and/or cellular) in a subject by administering the claimed sequences. (See, page 7, lines 9 to 20; page 12, line 28 to page 13, line 15; and Examples 4 and 7). Indeed, in December 1999, it was predictable and routine to evaluate whether an immune response was generated against a polypeptide antigen encoded by an administered polynucleotide, for example using the techniques and tools described above in paragraph 8. Furthermore, the skilled worker would know that

generating an immune response does not necessarily mean that the subject will be vaccinated – *i.e.*, protected against HIV infection or derive some therapeutic benefit. The skilled worker would also have known that immune responses are useful for numerous scientific purposes, such as laboratory assays, preparing reagents for virologic and immunologic studies, analyzing immune responses, and preparation of diagnostic kits. Therefore, a skilled worker would have known that the claimed sequences could be used for additional scientific purposes other than seeking protective immunity or a therapeutic benefit. In view of the guidance in the specification, the predictability and state of the art, and high level of the skilled worker, it is plain that it would have been routine to administer a polynucleotide and evaluate whether or not an immune response to the encoded polypeptide was generated in the subject.

12. Moreover, in the course of further work on HIV, the inventors have evaluated the immune responses generated upon administration of the claimed Gag-encoding polynucleotide constructs to subjects. The manuscript attached hereto (Exhibit B) shows that the claimed expression cassettes generate both humoral and cellular responses when made and administered to animal subjects as described in the specification. (See, for example, Figures of Exhibit B and text describing these Figures). Specifically, this manuscript demonstrates that neutralizing antibodies develop more rapidly in animals vaccinated with the claimed constructs; that these neutralizing antibodies correlated with lower peak viremia after pathogenic virus challenge; and that the claimed Gag-encoding constructs generate cellular immune responses. Thus, although not required by the claims, the claimed constructs are, in fact, able to generate potentially “protective” immune responses. Accordingly, a skilled worker could readily practice the claimed methods of generating an immune response in view of the teachings of the specification and state of the art as filed.

13. It would have also been routine to express the claimed Gag-encoding polynucleotides in stem cells or lymphoid progenitor cells. The guidance in the

specification in this regard is extensive. (See, Section 2.3.2 starting on page 61 of the specification). In addition, the level of skill in this field was very high at the time of filing, the state of the art sophisticated and the experimentation needed to get expression in lymphokine cells (such as stem cells and lymphoid progenitor cells) was routine using standard vectors (*e.g.*, plasmids such pBR322 and pBLUESCRIPT that include promoters and other control elements). Even a reference cited in the Office Action makes it clear that heterologous HIV polypeptide-encoding sequences can readily be introduced into and expressed in stem cells:

Other areas where gene transfer into hematopoietic cells is being investigated include human immunodeficiency virus (HIV) infection ... the importance of these studies cannot be over emphasized as they provide 'proof-in-principle' that gene-marked cells can survive and be expressed for extended periods of time once re-introduced into the host. (Prince, *Pathology* 30:335-347 at page 340, left column, emphasis added).

Therefore, the specification teaches a skilled worker how to express the claimed Gag-encoding sequences in stem cells or progenitors of lymphoid cells.

14. Finally, I believe that, following the teachings of the specification and guidance of the art, a skilled worker could have readily administered the claimed nucleic acids specification by a variety of modes including intramuscular, intradermal, mucosal and the like. The quantity of experimentation required to use alternatives to intramuscular delivery routes was quite low in December 1999. A skilled worker could have easily administered polynucleotides by a variety of routine methods known at the time of filing. For example, administration of polynucleotides encoding HIV antigens via intradermal and mucosal modes is described in Shiver et al. 1997 *Vaccine* 15:884-887 (Exhibit C) and Durrani et al. 1998 *J. Immunol. Methods* 220:93-103 (Exhibit D). These references are clearly representative of the high level of skill in the art and the fact that non-intramuscular modes of administration were considered predictable in December 1999 -- many of the examples gene delivery modes were also known. Furthermore, at the

time of filing, it was known in the art that administration of polynucleotide vaccines by diverse routes such as intradermal, transdermal, intranasal, oral and the like did not require special modifications to the coding sequence of the polynucleotide plasmid construct itself. The specification provides significant direction in these regards as well, for example on page 61 of the specification. Therefore, a skilled worker would have found the claimed expression cassette and sequences at least 90% identical to it to be useful for generating an immune response using diverse routes and methods. Thus, to the skilled worker, administering the claimed polynucleotides by any number of delivery routes would have been routine and required only minor experimentation.

15. In view of the foregoing facts regarding the routine nature of experimentation required to make and use the claimed constructs, the extensive direction provided by the specification, the straightforward nature of the invention, the presence of working examples, the high level of the skilled worker, the sophistication of the art, and the predictability (e.g., of determining sequences identity and immunogenicity) of the art, it is my unequivocal opinion that the specification enabled, in December 1999, a skilled worker to make and use the subject matter of the claims.

16. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

11/20/02  
Date

  
John J. Donnelly, Ph.D.

## CURRICULUM VITAE

### I. PERSONAL

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B. Address: 46 Fieldbrook Pl  
Moraga, CA 94556  
C. Home Telephone: (925)376-5602  
Office Telephone: (510)923-8371  
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E-mail: john\_donnelly@chiron.com

### II. EDUCATION

<u>School</u>	<u>Date</u>	<u>Field</u>	<u>Degree</u>
University of Pennsylvania	1971-1975	Biology	B.A.
University of Pennsylvania	1975-1979	Immunology	Ph.D.
US Army War College	2000-2002	Strategic studies	M.S.

### III. TRAINING

<u>Source</u>	<u>Date</u>	<u>Type</u>
Department of Ophthalmology John Hopkins University School of Medicine Baltimore, Maryland	1982	Postdoctoral Research Fellow (Preceptor: R.A. Prendergast, M.D.)
Department of Clinical Veterinary Medicine University of Cambridge Cambridge, England	1980-81	Postdoctoral Research Fellow (Preceptor: Prof. E.J.L. Soulsby, D.V.S.M., M.R.C.V.S., Ph.D.)

### IV. SOCIETY MEMBERSHIPS

American Association of Blood Banks  
American Association of Immunologists  
Association for Research in Vision and Ophthalmology  
British Society for Immunology  
New York Academy of Sciences  
Royal Society for Tropical Medicine and Hygiene

### V. ACADEMIC AND PROFESSIONAL HONORS

2000 President's Leadership Award, Chiron Corp.  
1976-79 NIH Predoctoral Traineeship  
1977 Fight for Sight Student Fellow  
1980-81 Fight for Sight Postdoctoral Research Fellow

1982 NIH Individual Postdoctoral Fellowship  
 1983 Robert E. Shoemaker Research Award, Pennsylvania  
     Academy of Ophthalmology and Otolaryngology  
 2000 President's Leadership Award, Chiron Research and Development

**VI. ACADEMIC EXPERIENCE**

**A. Within the last five years**

1988 - 1998 Adjunct Assistant Professor  
     Department of Ophthalmology  
     University of Pennsylvania School of Medicine  
     Philadelphia, Pennsylvania

**B. Prior to the last 5 years**

1983-88	Assistant Professor, Department of Ophthalmology University of Pennsylvania School of Medicine Philadelphia, Pennsylvania
1986-88	Graduate Group in Immunology University of Pennsylvania Philadelphia, Pennsylvania
1983-88	Graduate Group in Parasitology University of Pennsylvania Philadelphia, Pennsylvania

**VII. EMPLOYMENT HISTORY**

Position Title: Senior Director, Vaccine Research and Development  
     Department of immunology & Infectious Diseases  
     Chiron Research and Development  
     Chiron Corporation

Duration: July 2000-present

Brief Description of Significant Responsibilities:  
 Manage more than 20 Principal and Associate Scientists in research on HIV Vaccines and vaccine adjuvants and delivery. Direct Chiron HIV vaccine research and development program. Lead team responsible for externally financing HIV Vaccine R&D project; raised over \$42 million of outside funds, mostly from NIH, since 1999. Direct clinical serology laboratory supporting Phase I-II studies of N. meningitidis group B vaccine. Provide research support for clinical studies of therapeutic hepatitis B vaccine and Interleukin-2 therapy of HIV. Direct basic research on serologic markers for immunity to Neisseria meningitidis group B. Direct basic research in cancer immunotherapy. Responsibilities include direction of basic research, direction of preclinical studies, budgeting, contribution to regulatory documentation, and presentations to outside regulatory groups such as the FDA Vaccines and Related Biologicals Advisory Committee. Chair of Institutional Animal Care and Use Committee for Chiron Corp, responsible for Emeryville and Seattle sites.

Position Title: Acting Vice President, Vaccine Research and Development  
     Chiron Research and Development  
     Chiron Corporation

Duration: February - July 2000

From departure of Vice President until new Vice President brought in from Chiron Siena, managed more than 35 Principal and Associate Scientists in research on HIV Vaccines, HCV Vaccines, DNA Vaccines, Vaccine Adjuvants and Delivery, and cell culture and recombinant protein production. Restructured Vaccines Research Department to achieve fiscal balance. Retained key personnel while reducing workforce by 15%. Managed internal and external HIV vaccine research and development activities. Directed clinical serology laboratory supporting Phase III studies of meningitis C conjugate vaccine (Menjugate®). Provided research support for clinical studies of therapeutic hepatitis B vaccine and Interleukin-2 therapy of HIV. Directed basic research on serologic markers for immunity to Neisseria meningitidis group B. Responsibilities included direction of basic research, direction of preclinical studies, budgeting, contribution to regulatory documentation, and presentations to outside regulatory groups such as the FDA Vaccines and Related Biologicals Advisory Committee. Chaired Institutional Animal Care and Use Committee for Chiron Corp.

Position Title: Director, Vaccine Adjuvants Research  
Chiron Technologies  
Chiron Corporation

Duration: 1998-presentBrief Description of Significant Responsibilities:

Manage more than 30 Principal and Associate Scientists in research on vaccine adjuvants, induction of cytotoxic T cells, DNA vaccines for HIV and HCV, cancer immunotherapy, gene therapy with MuLV-based viral vectors, and bacterial vaccines. Direct internal and external adjuvant research programs. Responsibilities include direction of basic research, direction of preclinical studies, budgeting, contribution to regulatory documentation, and presentations to outside regulatory groups such as the FDA Vaccines and Related Biologicals Advisory Committee. Beginning in September 1999, chaired Institutional Animal Care and Use Committee for Chiron Corp.

Position Title: Associate Director, Immunology  
Dept. of Virus & Cell Biology  
Merck Research Laboratories

Duration: 1994-98Brief description of significant responsibilities:

Manage more than 10 Principal and Associate Scientists in basic research on DNA vaccines for influenza, HCV, and HPV, recombinant protein vaccines for Hepatitis B, vaccine adjuvants, and preclinical and clinical studies for Haemophilus influenzae type B and Streptococcus pneumoniae polysaccharide-protein conjugate vaccines. Studied cytotoxic T cell responses in nonhuman primates and cytokine responses in human subjects to experimental influenza DNA vaccines. Prepare regulatory documentation including preclinical sections of PLA's and Part III (Pharmacological Documentation) of MAA's for bacterial vaccines and combination vaccines (Liquid PedvaxHIB®, COMVAX®, New Process Pneumovax 23®). Chaired Institutional Animal Care and Use Committee for West Point site.

Position Title: Research Fellow  
Dept. of Virus & Cell Biology  
Merck Research Laboratories

Duration: 1988-94

Brief Description of Significant Responsibilities:

Supervise up to 8 Principal and Associate Scientists in research on mechanisms of induction of cytotoxic T lymphocytes, including immunization with DNA, evaluation of adjuvants for clinical use in vaccines, development of analytical/serological assays for support of clinical vaccine programs (HPV, HIV, Influenza), preclinical development of bacterial vaccines, and preclinical development of influenza DNA vaccines. Direct research/licensing program in vaccine adjuvants and delivery systems.

1980-81 Postdoctoral Research Fellow, Department of Clinical Veterinary Medicine  
University of Cambridge, Cambridge, England

1982 Postdoctoral Research Fellow, Department of Ophthalmology  
Johns Hopkins University School of Medicine  
Baltimore, Maryland

1983-88 Assistant Professor, Department of Ophthalmology  
University of Pennsylvania School of Medicine  
Philadelphia, Pennsylvania

IX. OTHER SKILLS, QUALITIES OR ACCOMPLISHMENTS

A. Membership on Peer Review Panels:

USAID Biotechnology/Immunology Panel	1988-1991
NIH/NIAID Review Committee for RFA NIH-NIAID-94-11,	
Basic Biology of Immune Responses for Vaccine Research	1994
NIH/NIAID Visual Sciences A Study Section, Ad hoc member	1997
NIH/NIDR Special Emphasis Panel on Oral Carcinoma	1997
USAID Schistosomiasis Vaccine Development Program Advisory Group, 4 year term beginning	1997
NIH/NIAID Vaccines Study Section, 3 year term beginning	1998

B. Editorial Boards:

Contributing Editor: Autoimmunity	1988-
Current Eye Research	1987-
Cellular Immunology	1986-
Investigative Ophthalmology and Visual Science	1981-
Journal of Immunology	1994-

C. Meetings Organized

IBC First Annual Conference on Genetic Vaccines	1995
IBC Second Annual Conference on Genetic Vaccines	1996
IBC 4th Annual International Conference on Mucosal Immunization	1996
IBC Third Annual Conference on Genetic Vaccines	1997
IBC Fourth Annual Conference on Genetic Vaccines	1998
2 <sup>nd</sup> Annual US Biotechnology Symposium	1999

D. Military Service:

Colonel, Medical Service Corps, U.S. Army Reserve

Blood Program Officer, Third United States Army (Forward), King Khalid  
Military City, Saudi Arabia, 12/22/90-4/1/91

X. PUBLICATIONS AND PATENTS

Donnelly, J.J., Rockey, J.H. and Soulsby, E.J.L.: Intraocular IgE antibody induced in guinea pigs with *Ascaris suum* larvae. *Invest. Ophthalmol. Vis. Sci.* 16: 976-981, 1977.

Rockey, J.H., Donnelly, J.J., Stromberg, B.E. and Soulsby, E.J.L.: Immunopathology of *Toxocara canis* and *Ascaris suum* infections of the eye: The role of the eosinophil. *Invest. Ophthalmol. Vis. Sci.* 18: 1172-1184, 1979.

Soulsby, E.J.L., Stromberg, B.E., Donnelly, J.J. and Rockey, J.H.: Intraocular immunoglobulin E induced by intravitreal infection with *Ascaris* and *Toxocara* spp. larvae. *Ophthal. Res.* 12: 45-53, 1980.

Rockey, J.H., Donnelly, J.J., Stromberg, B.E., Laties, A.M. and Soulsby, E.J.L.: Immunopathology of Ascarid infection of the eye: Role of IgE antibodies and mast cells. *Arch. Ophthalmol.* 99: 1831-1840, 1981.

Donnelly, J.J., Rockey, J.H., Bianco, A.E., and Soulsby, E.J.L.: Aqueous humor and serum IgE antibody in experimental ocular *Onchocerca* infection of guinea pigs. *Ophthal. Res.* 15: 61-67, 1983.

Rockey, J.H., John, T., Donnelly, J.J., McKenzie, D.F., Stromberg, B.E., and Soulsby, E.J.L.: In vitro interactions of eosinophils from ascarid-infected eyes with *A. suum* and *T. canis* larvae. *Invest. Ophthalmol. Vis. Sci.* 24: 1346-1357, 1983.

John, T., Donnelly, J.J. and Rockey, J.H.: Experimental ocular *Toxocara canis* and *Ascaris suum* infection: In vivo and in vitro study. *Trans. Pa. Acad. Ophthalmol. Otolaryngol.* 36: 131-137, 1983.

Attenburrow, D.P., Donnelly, J.J. and Soulsby, E.J.L.: Periodic ophthalmia (recurrent uveitis) of the horses: An evaluation of the etiological role of microfilariae and the clinical management of the condition. *Equine Vet. Journal* 15: 48-56, 1983.

Donnelly, J.J., Rockey, J.H., Bianco, A.E. and Soulsby, E.J.L.: Ocular immunopathologic findings of experimental onchocerciasis. *Arch. Ophthalmol.* 102: 628-634, 1984.

Donnelly, J.J. and Prendergast, R.A.: Local production of Ia-inducing activity in experimental immunogenic uveitis. *Cellular Immunology* 86: 557-561, 1984.

Khatami, M., Donnelly, J.J., John, T. and Rockey, J.H.: Vernal conjunctivitis. Model studies on guinea pigs immunized topically with fluoresceinyl ovalbumin. *Arch. Ophthalmol.* 102: 1683-1688, 1984.

Lok, J.B., Pollack, R.J., Cupp, E.W., Bernardo, M.J., Donnelly, J.J., and Albiez, E.J.: Development of third-stage larvae of *Onchocerca volvulus* and *O. lienalis* in vitro. *Tropenmedizin und Parasitologie* 35: 209-212, 1984.

Donnelly, J.J., Vogel, S.N. and Prendergast, R.A., Down-regulation of Ia expression on macrophages by Sea Star Factor. *Cellular Immunology* 90: 408-415, 1985.

Rockey, J.H., Donnelly, J.J., John, T., Khatami, M., Schwartzman, R.M., Stromberg, B.E., Bianco, A.E. and Soulsby, E.J.L.: IgE antibodies in ocular immunopathology. Third International Symposium on the Immunology and Immunopathology of the Eye. Masson, New York, pp.199-202, 1985.

Khatami, M., Donnelly, J.J. and Rockey, J.H.: Induction and down-regulation of conjunctival Type-I hypersensitivity reactions in guinea pigs sensitized topically with fluoresceinyl ovalbumin. Ophthalmic Research 17: 139-147, 1985.

Donnelly, J.J., Li, W., Rockey, J.H. and Prendergast, R.A.: Induction of class II (Ia) alloantigen expression on corneal endothelium *in vivo* and *in vitro*. Invest. Ophthalmol. Vis. Sci. 26: 575-580, 1985.

Donnelly, J.J., Rockey, J.H., Taylor, H.R. and Soulsby, E.J.L.: Onchocerciasis: Experimental models of ocular disease. Reviews of Infectious Diseases 7: 820-825, 1985.

Donnelly, J.J., Taylor, H.R., Young, E.M., Khatami, M., Lok, J.B. and Rockey, J.H.: Experimental ocular onchocerciasis in cynomolgus monkeys. Invest. Ophthalmol. Vis. Sci. 27: 492-499, 1986.

Sakla, A.A., Donnelly, J.J., Lok, J.B., Khatami, M. and Rockey, J.H.: Punctate keratitis induced by subconjunctivally injected microfilariae of *Onchocerca lienalis*. Arch. Ophthalmol. 104: 894-898, 1986.

James, E.R., Smith, B. and Donnelly, J.J.: Invasion of the mouse eye by *Onchocerca* microfilariae. Trop. Med. and Parasitol. 37: 359-360, 1986.

Donnelly, J.J., Sakla, A.A., Hill, D.E., Lok, J.B., Khatami, M. and Rockey, J.H.: Effects of diethylcarbamazine citrate and anti-inflammatory drugs on experimental onchocercal punctate keratitis. Ophthalmic Research. 19: 129-136, 1987.

Lok, J.B., Pollack, R.J. and Donnelly, J.J.: Studies of the growth-regulating effects of Ivermectin on larval *O. lienalis* *in vitro*. J. Parasitol. 73: 80-84, 1987.

John, T., Barsky, H.J., Donnelly, J.J. and Rockey, J.H.: Retinal pigment epitheliopathy and neuroretinal degeneration in ascarid-infected eyes. Invest. Ophthalmol. Vis. Sci. 28: 1583-1598, 1987.

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Donnelly, J.J., Deck, R.R., Liu, M.A.: Immunogenicity of a *Haemophilus influenzae* polysaccharide-*Neisseria meningitidis* outer membrane protein complex conjugate vaccine. *Journal of Immunology.* **145**: 3071-3079, 1990.

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Semba, R.D., Donnelly, J.J., Young, E., Green, W.R., Scott, A.L., Taylor, H.R.: Experimental ocular onchocerciasis in cynomolgus monkeys. IV. Chorioretinitis elicited by Onchocerca microfilariae. *Invest Ophthalmol Vis. Sci.* **32**:1499-1507, 1991.

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Liu, M.A., Friedman, A., Oliff, A.I., Tai, J., Martinez, D., Deck, R.R., Shieh, J. T.-C., Jenkins, T.D., Donnelly, J.J., Hawe, L.A.: A vaccine carrier derived from *Neisseria meningitidis*: with mitogenic activity for lymphocytes. *Proc. Nat. Acad. Sci. (USA)* **89**:4633-37, 1992.

Ulmer, J.B., Burke, C.J., Shi, C., Friedman, A., Donnelly, J.J., Liu, M.A.: Pore formation and mitogenicity in red blood cells by the Class 2 protein of *Neisseria meningitidis*. *J. Biol. Chem.* **267**:19266-19271, 1992.

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